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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,517	05/21/2001	Tibor Gizur	21838	9138

535 7590 12/18/2002  
THE FIRM OF KARL F ROSS  
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EXAMINER
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OH, TAYLOR V

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 12/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/856,517

Applicant(s)

GIZUR ET AL.

Examiner

Taylor Victor Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10 is/are rejected.
- 7) ☒ Claim(s) 11-17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Claim Rejections - 35 USC § 112***

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a hydrogenation catalyst, such as rhodium, palladium, Raney nickel, or cobalt catalyst on activated carbon, does not reasonably provide enablement for all the hydrogenation catalysts in the field of organic chemistry. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the hydrogenation catalysts in the field of organic chemistry unrelated to the invention commensurate in scope with these claims.

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According to the specification, the examples of the hydrogenation catalyst are described in the followings: as rhodium, palladium, Raney nickel, and cobalt catalyst on activated carbon. Not all the hydrogenation catalysts in the field of organic chemistry are related to the invention. Therefore, an appropriate correction is required.

Furthermore, there are "foreman factors or Wands factors" regarding the presence or absence of working examples because the preparation of 1-(aminomethyl)cyclohexyl-acetic acid (see page 6) has used only one example of palladium catalyst shown in the specification (page 6). Thus, the specification has failed to provide sufficient working examples to support the broad spectrum of the hydrogenation catalysts. Catalyst compositions represent an unpredictable aspect in the art of organic chemistry. See Exparte sizto, 9 USPQ2d 2081 (Bd. Of App. And Inter.

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March 1988). In addition, more than routine experimentation is required and involved (second foremen factor).

See In re Armbruster 185 USPQ 204 (CCPA 1985) and Angstadt et al , 190 USPQ 152, (CCPA 1990).

Claims 11-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Rylander et al (U.S. 3,253,039) teaches the catalytic hydrogenation of organic nitrocompounds such as nitrophenylacetic acid in the presence of Ag and Pt catalysts at a temperature of from 20 to 100° C.

Knifton (U.S. 3,766,271) teaches a process for reducing nitro-paraffinics containing 3 to 20 carbon atoms by heating nitroparaffins at a temperature of from 35 to 150° C. in a highly alkaline non-aqueous medium with a ruthenium or iron catalyst.

Rosenthal (U.S. 3,594,419) teaches a process for converting a nitroparaffin to the corresponding primary amine by the reaction of hydrogen in the presence of ammonia and a hydrogenation catalyst.

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Satzinger et al (U.S. 4,024,175) teaches a preparation of 1- aminomethyl-1-cyclohexane-acetic acid by reacting monomethyl 1,1-cyclohexane-diacetate with triethylamine, and further adding hydrochloric acid and then extracting the resultant product with chloroform, thereby obtaining the desired product.

Butler et al (U.S. 4,894,476) teaches a preparation of gabapentin by dissolving gabapentin monohydrate in methanol at 50 to 60<sup>0</sup> C.; diluting with 2-propanol and cooling to 0<sup>0</sup> C. to -10<sup>0</sup> C.; and centrifuging the slurry and drying the precipitate of gabapentin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 703-305-0809. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-2742 for regular communications and 703-305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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December 12, 2002

*Alan L. Rotman*

ALAN L. ROTMAN  
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